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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------------|---------------------|------------------|
| 10/562,842 | 12/29/2005 | Clara Lucia Garcia-Rodenas | 112701-696 | 5990 |

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| 29157 | 7590 | 02/22/2008 |
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| EXAMINER | |
| WARE, DEBORAH K | |

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| ART UNIT | PAPER NUMBER |
| 1651 | |

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| NOTIFICATION DATE | DELIVERY MODE |
| 02/22/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/562,842 | Applicant(s) ALPHEY, LUKE | |
| | Examiner Deborah K. Ware | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5 and 7-9 are pending.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 13, 2007, was filed and received. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

The amendment filed November 19, 2007, and extension of time filed therewith, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over previously cited Portman (US 6207638) in view of newly cited Mallee et al (US 6620778) and previously cited Kopf et al (6875459).

Claims are drawn to a method for preventing and/or improving metabolic conditions associated with Type 2 diabetes mellitus in a person comprising administering to the person a composition comprising a protein source consisting essentially of intact whey proteins in an amount of 21 to 40 % dry wt or administering in an amount of 0.1 g intact whey proteins per kg body wt.

Portman teaches treating a person with type II diabetes comprising administering a nutritional composition comprising whey protein and casein and other ingredients.

Mallee et al teach that whey protein is an important cysteine source of which elevates glutathion levels in a person and glutathion plays a role in the prevention of cataracts, note col. 1, lines 30-35 and col. 4, line 35.

Kopf et al teach that a casein-depleted fraction containing whey proteins which contains soluble components for use in treating diabetes, note col. 7, lines 1-20.

The claims differ from Portman in that casein is not required by the claimed method and the active ingredient is intact whey protein.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a person with type II diabetes administering a nutritional composition comprising whey protein as disclosed by Portman but in the absence of casein as disclosed by Mallee et al and Kopf et al in order to prevent or improve metabolic conditions associated with type 2 diabetes melitus in a person. Mallee et al clearly disclose that cysteine residues are comprised by whey protein and are useful for improving cataracts which are a condition associated with type II diabetes. One of ordinary skill in the art would have been motivated to increase the percentage by dry wt of a nutritional composition or dosage of Portman to enhance treatment of diabetes because Mallee et al and Kopf et al teach that whey proteins are useful. Mallee et al further explains that the cystiene residues are the active components in the whey which provide the expected successful result. One of skill would have been motivated to replace all of the casein in Portman with increased amounts of whey in view of the disclosures of Mallee et al and Kopf et al.

To optimize amounts to 0.1 to 0.8 g intact whey protein and/or to increase the amount of protein in the composition of Portman to a range of from 25 to 35% by wt is clearly within the

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skill of an ordinary artisan. Mallee et al clearly teach that at 20% is a desirable amount by weight. Sweet whey protein is well known and would have been an obvious modification of a nutritional supplement because it taste better than casein and would have been expected to provide successful results. The composition is disclosed to be in varied forms including a powder and to further include vitamins and other ingredients such as lecithin. The claims are prima facie obvious over the newly applied art rejection.

Response to Arguments

Applicants' arguments were deemed persuasive over the previous art rejections but with the newly discovered reference of Mallee et al the claims are maintained to be prima facie obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-1449 Form and/or PTO-892 Form. Therefore, the claims are properly rejected.

The remaining references cited on the enclosed Forms are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware
February 16, 2008